Exhibit 1

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

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TAKEDA PHARMACEUTICAL CO., LTD., TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, AND TAKEDA PHARMACEUTICALS AMERICA, INC.

Plaintiffs

Case No:
3:11-CV-00840-JCS

V.

HANDA PHARMACEUTICALS, LLC

Defendant

- - - - - - - - - - - - - - - - x

VIDEOTAPED DEPOSITION OF
ALLAN MYERSON, PH.D.
Tuesday, November 15, 2011
9:41 a.m.

Finnegan Henderson
55 Cambridge Parkway
Boston, Massachusetts

Deborah Roth, RPR/CSR

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

- - - - - - - - - - - - - - - - - x

TAKEDA PHARMACEUTICAL CO., LTD., TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, AND TAKEDA PHARMACEUTICALS AMERICA, INC.

Plaintiffs

Case No: 3:11-CV-01609-JCS

V.

ANCHEN PHARMACEUTICALS, INC. AND TWI PHARMACEUTICALS, INC.

Defendants

- - - - - - - - - - - - - - - - - x

VIDEOTAPED DEPOSITION OF
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TAKEDA PHARMACEUTICAL CO., LTD., TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, AND TAKEDA PHARMACEUTICALS AMERICA, INC.

Plaintiffs

Case No.: 3:11-cv-01610-CRB

V.

IMPAX LABORATORIES, INC.

Defendant

- x

VIDEOTAPED DEPOSITION OF
ALLAN MYERSON, PH.D.
Tuesday, November 15, 2011
9:41 a.m.

Finnegan Henderson
55 Cambridge Parkway
Boston, Massachusetts

Deborah Roth, RPR/CSR

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ALSO PRESENT: Jody Urbati, Videographer

INDEX

WITNESS: ALLAN MYERSON, PH.D.

P-R-O-C-E-E-D-I-N-G-S

THE VIDEOGRAPHER: This is the video operator speaking, Jodi Urbati, of Merrill Legal Solutions, 225 Varick Street, New York, New York 10014.

Today is November 15th, 2011. The time is 9:41 a.m.

We are at the offices of Finnegan Henderson, Cambridge, Massachusetts, to take the videotaped deposition of Allan Myerson in the matter of Takeda Pharmaceutical Company, LTD, versus Handa Pharmaceuticals, LLC; Anchen Pharmaceuticals, Inc., and TWI Pharmaceuticals, Inc.; and Impax Laboratories, Inc., in the United States District Court, Northern District of California, San Francisco Division.

Will counsel please introduce themselves for the record, and then the reporter, Deborah Roth, of Merrill Legal Solutions will swear in the witness.

MR. ACKER: Eric Acker of Morrison & Foerster on behalf of Impax Laboratories.

MS. TAKAHASHI: Heather Takahashi of

Munger Tolles & Olson on behalf of the Takeda parties and the witness, Dr. Myerson.

MR. DANE: Ted Dane also Munger Tolles & Olson.

MR. LeMEILLEUR: Payson LeMeilleur of Knobbe Martens on behalf of the defendant, Handa Pharmaceuticals.

MR. MIZERK: Don Mizerk of Husch Blackwell on behalf of TWI Pharmaceuticals and Anchen Pharmaceuticals.

ALLAN MYERSON, Ph.D.,

having been satisfactorily identified by the production of his Massachusetts driver's license, and duly sworn by the Notary Public, was examined and testified as follows:

EXAMINATION

BY MR. ACKER:

Q. Good morning, Doctor.

A. Good morning.

Q. As I just indicated, my name is Eric Acker and I represent Impax Laboratories. I appreciate you taking time this morning to answer some of ours questions.

You've had your deposition taken

So, normally, while you expect the major peaks to be the major peaks on occasion -- well, quite frequently, relative intensity will change. So it's usually not used as a -- nearly as much as peak location in determining whether a form is present or not.

Certainly, the larger intensity peaks should still be the larger intensity peaks, but the order sometimes will change; particularly, due to preferred orientation effects.

Q. And is that the full extent of the experimental error that you believe one of skill in the art would expected to see in 1999 or 2000 in an XRPD experiment that is up to plus or minus .2 degrees?

A. Plus or minus .2 degrees two theta. That's correct.

Q. And this experimental error in the two theta values, after you did the analysis would result in a corresponding error in the d-values, correct? d-spacings?

A. Yes. It would not be a linear.

It's not linear because we have to

solve Bragg's law; and, of course, what you would see is that you would have a bigger variation in the d-spacings at low angles than you would at high angles because that's just how the calculation would work.

Q. And the result of .2 degrees in the two theta angles or two theta degrees would result in a larger error in the spacings, correct?

A. No. Actually, that's not correct.

Q. In the d-spacings?

A. No, it would not.

Q. As a numerical value, it would result in a larger error in the d-spacings?

A. No. That's incorrect.

As I just testified, the change in the d-spacings would be a function of the angle. You would have a larger than .2 error in the -- in the low angles, which are the high d-spacings, and a much smaller than .2 error in the higher angles, which are the -- which are the smaller d-spacings.

Q. But the way that you would determine what the error in the d-spacings were based on some error in the two theta angles would be to

do the analysis under Bragg's law?
A. Exactly right. You would calculate the delta d for each angle by substituting in the Bragg's law equation, right, you'd say that Bragg's law is n lambda equals 2d sin theta, right?
So you would just substitute -- you would get a difference of sin theta plus .1 and sin theta minus .1. You know, you could just make an equation, delta d, have two things. It would be very simple to do. It's done all the time.
Q. So is it your opinion that one of skill in the art in 1999 or 2000, when running an XRPD experiment multiple times on the same crystal, would expect to see up to a .2 degree scientific error in the two theta results?
A. Yes.
Q. And would it also be your opinion that one in nineteen ninety -- or 2000, if one were to run multiple XRPD analysis on different crystals of the same type, they would see the same level of scientific error?
A. Well, I'm sorry. What do you mean by

A. Yes.
Q. Claim 1 of the '058 requires specific characteristic peaks of interplanar spacings or d-values as calculated Bragg's law for the claimed compound, correct?
A. It requires a specific set of d-spacings for the same compound. That's correct.
Q. And what is set out in the claim are 11 specific characteristic peaks measured out to the hundreds decimal point, right?
A. Two decimal places, correct.
Q. And there's no mention in the claim of experimental error, right?
A. That's correct.
Q. No use of the word "about," right?
A. That's correct.
Q. No use of the word "approximately"?
A. That's correct.
Q. No other qualifying language of any sort in the claim, right?
A. That's correct.
Q. Just 11 measurements of interplanar spacings or d-values measured out two decimal

points, right?

A. That's correct.

Q. And that's -- the same is true for claim 2, correct?

A. That's correct.

Q. Again, there's no mention, no qualifying language such as "about" or "approximately" in claim 2, correct?

A. That's correct.

Q. And there's no mention of experimental error in claim 2, correct?

A. That's correct.

Q. Again, just 11 d-spacing measurements measured out to two decimal points, right?

A. That's correct.

Q. And you agree that the written description of the patent plays the key role in determining what one of skill in the art would believe that a claim term meant?

A. You mean the specification?

Q. I'm talking about the claims and the specifications?

A. Right. The patent itself?

Q. Yes.

A. Right. I agree with that.
Q. And would you agree with me that the claims are the most important thing to review in determining what is the meets and bounds of an invention?
A. Well, the claim, certainly, is the most important thing, but you interpret the claim in light of the specification.
Q. And then next in line would be looking at the specification; that is, the written narrative in the patent, published patent, before the claims, right?
A. Correct.
Q. And then you also might look at the prosecution history to determine what claim terms may mean, right?
A. That's possible, yes.
Q. And that is all -- you understand that's all as what is referred to as intrinsic evidence; that is, the claims, the specification, and the file history?
You understand that?
A. Yes.
Q. And you also understand that what you

have done in this case with respect to this term is you have looked to extrinsic evidence to determine what you believe the claim term to mean, right?

A. Yes.

Q. And extrinsic evidence, that is evidence that's not in the claims, right?

A. Correct.

Q. And it's evidence that's not in the specification, correct?

A. Correct.

Q. And it's evidence that's not in the file history, right?

A. Not that I recall.

Q. And you would agree that in addition to there being no mention of experimental error anywhere in the claims, there's no mention anywhere in the specification of experimental error, right?

A. That's correct.

Q. You would also agree with me that there is no mention in the file history for the '058 patent that one of skill in the art should account for experimental error in the

d-spacing measurements, correct?

A. I don't, as I sit here, recall what it says in the file history on that particular subject, but I don't recall such a -- any statement, but I can't recall.

Q. Okay. Just so we're clear, you would agree that there's nothing in the claims or nothing in the specification about experimental error, right?

A. That's correct.

Q. And you have no recollection of anything in the file history about experimental error, correct?

A. That's correct.

Q. And your opinion that experimental error should be accounted for in defining the claim term is based solely on extrinsic evidence, right?

MS. TAKAHASHI: Objection. Mischaracterizes the witness' testimony.

A. On intrinsic evidence and my own knowledge and experience.

Q. Okay. And intrinsic evidence is documents that you've cited in your

declaration, correct?

A. Yes.

Q. And your own experience would also be extrinsic evidence, correct?

A. Yes.

Q. So there's nothing anywhere in the extrinsic -- intrinsic evidence for the '058 patent that would lead one of skill in the art in 1999 or 2000 to believe that they should count for some experimental error in the d-spacing values, right?

A. Again, my opinion, one of ordinary skill would understand that d-spacing values are not accurate to two decimal places and would understand that there's error in there, but I guess you would call that extrinsic evidence, as well.

Q. It's -- actually, the Federal Circuit has, not me, but let me ask the question again.

There's nothing in the intrinsic records, the claims, the specification of the file history that tells one of skill in the art in 1999 or 2000 that they should account

for experimental error in the d-spacing values listed in claims 1 and 2 of the '058 patent?

A. There's nothing in the patent specification or the claims. I agree with that.

Q. Okay. Let's look at the data that's actually in the '058 patent, if we could.

If we start -- if we look at column 7 and you -- column 7, lines 15 to 18, you see there, there's a reference there to the actual machine, the XRPD machine that was used --

A. Yes.

Q. -- to do the analysis?

A. Yes.

Q. And it reads, "X-Ray powder diffraction was determined using the x-ray powder diffraction meter Rigaku RINT2500 (ultraX18) No. PX-3."

Do you see that?

A. Yes.

Q. And that's just a reference to the XRPD machine that was used, correct?

A. That's correct.

columns -- column 10, lines 16 and 17.

A. There are actually d-spacings reported in two places in this example --

Q. Okay.

A. -- starting on column 9, line 1, which is for the wet crystal. There are 4 d-spacings -- 5 d-spacings reported.

And then later on, there's a further processing, and then there's another sort of d-spacings reported, which are the ones that you just mentioned.

Q. And that's in column 10, lines --

A. I'm sorry.

Actually, continuing, there's additional d-spacings in column 9, line 20; and in column 9, line 58; followed by the d-spacings in column 10, lines 14 and 15.

Q. And do you understand that the d-spacings in column 10, lines 16 and 17 are the d-spacings of the final product, the final crystal?

A. Those are the d-spacings reported in the claim, yes.

Q. So what it reads is, at column 10,

lines 14 to 17, "The crystal yielded a powder x-ray diffraction pattern with characteristic peaks appearing at powder x-ray diffraction interplanar spacings d of 11.68, 6.77, 5.84, 5.73, 4.43, 4.09, 3.94, 3.89, 3.69, 3.41, and 3.11 Ångstrom"; is that right?

A. That's correct.

Q. And those are the exact d-spacings that are claimed in claim 1 of the '058 patent, right?

A. Yes, they are.

Q. There's no variation whatsoever between the d-spacings in reference example 4 and the claim -- claim 1 of the '058, right?

A. I would add there's no difference in the d-spacings in reference example 4 shown in lines 16 and 17 with the claims.

However, the d-spacings shown previously are -- have differences.

Q. And you understand that the earlier d-spacings are XRPD analysis of products of the experiment before you get to the final crystal that's reported in column 10 at lines 15 through 18?

MS. TAKAHASHI: Objection. Vague.
A. (Witness reviewing document.)
The x-ray diffraction peaks reported prior to the final ones reported in there are for the title compound in less pure versions because what they're doing is recrystallizing it multiple times to get to a final purity and then doing a final x-ray diffraction.
So it actually is the correct compound, and it is -- does contain, apparently, at least a portion of the correct crystalline form, but it's not the final product.
Q. And in the final product are the d-spacings that we read a minute ago that are the exact same d-spacings to two decimal points as in the claim 1 of the '058, right?
A. That's correct.
Q. There's no variation whatsoever?
A. That's correct. They're the same.
Q. And if you go to example 1, beginning on column 10 and going to column 11, again, that's a preparation of crystal (R)-lansoprazole; and, again, no d-values are

the two decimal points, the results for the two theta values or the d-spacing values are identical, it's true that there is no experimental error between the XRPD analysis in reference example 4 and in example 2 of the '058, correct?

A. No. That's actually an incorrect statement.

Q. Well, can you point to any specific d-value and say that there is a different d-value obtained because of experimental error?

A. No, but that's not the question you asked.

The question you asked was that there was no experimental error, which is incorrect, okay.

Q. Well, let's back up.

We have two experiments to prepare crystalline hydrate (R)-lansoprazole: one in reference 4 and one in example 2 --

A. Correct.

Q. -- of the '058, correct?

A. Correct.

Q. Different methods -- we can agree that different methods were used to prepare the crystal in reference example 4 and the crystal in example 2, correct?
A. Correct.
Q. Once the experiment was completed and there was crystalline hydrate (R)-lansoprazole in each of those experiments, XRPD analysis was done on each of the two crystals, right?
A. Correct.
Q. And the d-values obtained, the 11 d-values obtained for those crystals were identical to two decimal points, correct?
A. That's correct. Identical to two decimal places when you round the second set to two decimal places, correct.
Q. And they not only were identical to one another to two decimal points, they were also identical to the d-spacings that are set forth in claim 1 of the '058, right?
A. Right. But, obviously, the claim is not an experiment. It's a claim.
Q. So one of skill in the art in 1999 or 2000, in looking at this data, would see that

there were two methods used to prepare crystalline hydrate (R)-lansoprazole: one in reference example 4 and one in example 2, and the exact same d-values to two decimal points were obtained that matched exactly to the d-values in claim 1 of the '058, right?
A. That's correct.
Q. So given that data, in your opinion, is there anywhere in the data of the '058 patent that would cause one of skill in the art to believe that they should add experimental error into the definition for claim 1 of the '058 patent?
A. Nothing in the data. It would be based on the knowledge and experience of one of ordinary skill who understands x-ray diffraction analysis.
Q. So, again, extrinsic evidence to the '058 specification and its claims, correct?
A. Correct.
MR. ACKER: Why don't we take five minutes.
THE VIDEOGRAPHER: Off the record, 10:26 a.m.

Q. So let me try again.
In your opinion, the phrase "'melting start temperature' means 'the temperature at which crystals start to melt, represented by the onset temperature of melting as measured by DSC.'"
And that is your opinion, correct?
A. Correct.
Q. And when you talk about the term "melting start temperature," you're talking about the term in the claims 9 and 10 of the '668 patent, correct? And if you need to take a look --
MS. TAKAHASHI: It's tab 4.
Q. -- tab 4 of your --
A. I'm sorry. What claim numbers?
Q. Claims 9 and 10.
A. That's correct.
Q. And can you point to a single scientific paper, article, or other reference other than the '688 patent that uses or defines the term "melting start temperature"?
MS. TAKAHASHI: Objection. Ambiguous.

A. I believe I provided this in some of the extrinsic evidence attached in here.

The -- it's quite a common use, "melting start temperature."

Q. Those words, "melting start temperature"?

A. Oh, I don't know if -- the concept. I'm not sure if they say exactly the same words.

Q. So let me ask you again.

Are you -- can you point to a single scientific paper, article, or other reference other than the '668 patent that uses the specific term "melting start temperature"?

MS. TAKAHASHI: Objection. Asked and answered.

A. Yeah. Again, I would have to look at the extrinsic evidence I cite in support of this to see what exact language they use.

In my opinion, if they don't use that exact language, they use synonymous language that, in my opinion, means the same thing.

Q. Okay. Let's take a look at

A. Yeah. I would, actually, just for completeness, finish the sentence that says "except as defined otherwise."

Q. Okay. But is there anywhere in this section 741, can we find the term "melting start temperature"?

A. There is -- the -- it doesn't say "melting start temperature." It says defined -- excuse me.

There's a quote that I have in paragraph 73 from here which says, "The temperature at which the column of the substance under test is observed to collapse definitely against the side of the tube at any point as defined as the beginning of melting"; and, to me, "beginning" and "start" mean the same thing.

So I consider that to be evidence for "melting start temperature."

Q. Okay. And let's go back to the USP.

And that quote is actually the last full paragraph in the column under 741, and it reads, "The temperature at which the column of the substance under test is observed to

collapse definitively [sic] against the side of the tube at any point is defined as the beginning of melting, and the temperature at which the test substance becomes liquid throughout is defined as the end of melting or the 'melting point.'"

MS. TAKAHASHI: Objection. Misstates document.

Q. Did I read that correctly?

A. I'm sorry. I wasn't actually looking at the document while you were reading. Where --

Q. If you go to column -- the 741, melting range, starting temperature, if you go down to the last full paragraph.

MR. ACKER: I think he wants you to help him out there.

MS. TAKAHASHI: Right here. (Indicating.)

THE WITNESS: Okay.

A. Right. And the final sentence says, "The two temperatures fall within the limits of the melting range."

Q. But in that sentence that we just read,

there's no mention of the term -- or the term "melting start temperature" is not there?

A. The exact words "melting start temperature" are not there. But, again, I would say "beginning" and "start" are synonymous.

So I consider beginning of melting to be a synonym of "melting start."

Q. And the method that is described as being used there is not DSC, right?

A. In this particular example, that's correct. It's not DSC.

Q. In fact, nowhere in this section of the USP, section 741, is there a description of using DSC to measure melting start temperature, right?

A. Not in --

MS. TAKAHASHI: Objection. Ambiguous.

A. Not in this document, that's correct. This is not talking about DSC.

Q. So the first document you referenced, the 1995 USP, section 741, Melting Range or Temperature, we can agree that there is

nowhere in that section the term "melting start temperature," right?

MS. TAKAHASHI: Objection. Asked and answered.

A. Well, as I've previously said, the words "melting start temperature" don't appear, but the synonymous words "beginning of melting" appear.

Q. And nowhere in that section is there a reference to using DSC to measure melting start temperature, correct?

MS. TAKAHASHI: Objection. Asked and answered.

A. Again, DSC does not appear in this document.

Q. And if we go back to that section that we just looked at, it's really talking about a range between the beginning of melting and the end of melting, right?

A. That's correct. All melting points are reported as a range.

Q. So it's your opinion that all melting points are reported in range form?

A. They should be because no method of --

no method of measurement of melting doesn't measure a range.

Q. And what this section is talking about -- what technique is this section talking about to determine the beginning of melting?

A. This is a -- this is a capillary method. This is something I used to use when I was a student. This is the old method they used to use, put a capillary tube in an oil bath and observe visually.

Q. So you put your substance in a capillary tube and actually heat it in oil bath; is that right?

A. That's correct.

Q. And then you observe the substance while it's being heated, correct?

A. Right.

Q. And when -- according to the USP, when the substance is observed to collapse definitively [sic] against the side of the tube, that point is defined as the beginning of the melting, correct?

MS. TAKAHASHI: Objection.

Misstates the document.

A. Yeah. The document -- actually, the document says that, yeah, when "...the column of the substance under test is observed to collapse definitely against the side of the tube at any point is defined as the beginning of melting."

And if you do these experiments, actually, and you watch, I mean, your goal is to see the beginning, which is what they describe here; and when something is fully melted, you know it's melted because you see a meniscus because it's become liquid.

It's a very tedious experiment to do, and I'm glad that I don't have to do them anymore.

Q. But the document you're relying on to help define the term "melting start temperature" talks about using this capillary method and actually observing this -- what is the term called the "beginning of melting" and the "end of melting," right?

MS. TAKAHASHI: Objection. Misstates the witness' testimony.

A. The document is using the capillary method, and it defines the "beginning of melting," which is the term that we're looking to define, the "melting start temperature," which I believe is synonymous; and, in fact, no matter what device is used, the beginning of melting is still the beginning of melting.

Q. But, again, we can agree that the term "melting start temperature" is nowhere in this document, and the use of DSC is nowhere in this document?

MS. TAKAHASHI: Objection. Compound. Asked and answered.

A. Yes. Well, as I've previously answered, the term -- the words "melting start temperature" are not there, but "beginning of melting" are, which is a synonym, and DSC is not mentioned. That's correct.

Q. So let's look at the next document that you cite, which is the USP for 2005, Exhibit 23.

Now, this document, the USP for 2005, would not have been available to one of skill in the art to review in 1999 or 2000,

Q. There is a reference in this section to the use of DSC, correct?

A. Correct.

Q. But as with the other section of the USP from 2005, one of skill in the art would not have had access to this document in 1999 or 2000, right?

A. This document, that's correct.

Q. And in this section, section 891, there's no mention of a melting start temperature anywhere, right?

MS. TAKAHASHI: Objection. Ambiguous.

A. Again, this says, "In the case of melting, both an 'onset' and a 'peak' temperature can be determined objectively..."

"Onset" and "melting start" are the same thing. They're synonymous.

Q. And you base your opinion that "onset" and "melting start temperature" are the same thing based on anything other than your opinion?

A. My knowledge of the English language, and that's my opinion.

That's -- I mean, synonyms are synonyms. "Start"; "beginning"; and "onset" all mean the same thing.

Q. But can you point to any other reference other than your interpretation of the English language to equate the word "onset" with the term "melting start temperature"?

A. I imagine if you looked in Roget's Thesaurus, which I didn't do, you might find that these things are considered to be synonyms, the words -- the initial words "beginning"; "onset"; and "start," though not necessarily connected to the word "melting point."

Q. So let's look at the reference under "Transition Temperature."

If you go to the sentence that begins "In the case of melting," do you have that sentence?

A. Where -- I'm sorry. Where are we looking?

Oh, I see. Yeah. Okay.

Q. Do you have that sentence?

A. Yes.
Q. And it reads, "In the case of melting, both an 'onset' and a 'peak' temperature can be determined objectively and reproducibly, often to within a few tenths of a degree."
And we can agree that the words "melting start temperature" aren't in that sentence, correct?
A. Again, my answer is the same, that the term "onset" is the synonym for the "start temperature," and it's exactly describing the melting onset and the peak.
Q. And then it continues, "While these temperatures are useful for characterizing substances," and these temperatures are -- and "these temperatures are useful for characterizing substances, and the difference between the two temperatures is indicative of purity, the values cannot be correlated with subjective, visual 'melting-range' values..."
Do you see that?
A. Yes, I do.
Q. And what do you understand that to mean, that those temperatures "cannot be

correlated with subjective, visual 'melting-range' values"?

A. It says what it means.

The fact is that when you do melting range values with your eye, your eye is pretty good, but it's not as accurate as automated methods. So you can't necessarily correlate your data from a DSC with any visual data.

It's -- my analogy might be if you tried to visually pick peaks on a graph and try to correlate that with what peak picking software that used statistical analysis will give you, you get different results because people's eyes fool them; and so that's why -- that's why they call it subjective.

Q. And what they're talking about there, or one of the techniques they're talking about there, is the capillary method that you described that was set out in the 1995 USP, correct?

MS. TAKAHASHI: Objection. Ambiguous.

A. That's correct.

Q. And so what the USP in 2005 is saying,

MR. ACKER: Do you want to testify for him, or do you want to let him answer?
MS. TAKAHASHI: I object to the form of the question.
A. I'm sorry. Could I hear the question again?
Q. Sure.
Have we now gone through all of the extrinsic references that you have cited in your declaration to support your interpretation of the term "melting start temperature"?
A. I lost the rest of my declaration. It's here somewhere.
Q. Do you want to take a minute and sort it out?
A. Here we go. Okay. To the other -- I'm sorry. You said extrinsic evidence?
Q. Yes, sir.
A. That's all the extrinsic evidence that I have cited.
Q. And that being the 1995 and the 2005 versions of the USP, right?
A. Correct.
Q. Now, let's take a look at the

specification itself of the '668. I think it's tab 4.

A. I'm just trying to get myself in order.

Q. Okay.

A. Okay. Tab 4?

Q. I believe so.

A. Okay.

Q. And if we go to column 12.

A. Yes.

Q. And if we look at the line 4, it reads "as used herein."

Do you see that?

A. Yes.

Q. "As used herein, the 'melting start temperature' refers to the temperature at which crystals start to melt when heated under, for example, the DSC measurement conditions to be mentioned below."

Do you see that?

A. Yes.

Q. And you rely on that language in your declaration to support your definition of "melting start temperature," correct?

A. That's correct.

Q. Now, the reference to the use of DSC is illustrative in that sentence, correct?
MS. TAKAHASHI: Objection. Ambiguous.
A. It says, "...when heated under, for example, the DSC measurement conditions to be mentioned below." So that implies that other methods could be used.
Q. And so the inventors here are simply giving one example of a method that could be used, DSC, but they're not saying that other methods should not be used, right?
A. That's correct.
Q. Now, in your definition of the term "melting start temperature," you indicate or your definition requires that DSC be used to measure melting start temperature, correct?
Can you take a look at 86, paragraph 86, 86C?
A. Uh-huh. Well, what I say is, in my opinion, the phrase "melting start temperature" means the temperature at which crystals start to melt represented by the onset temperature of melting as measured by

differential scanning calorimetry.
Q. So your definition of "melting start temperature" does not allow for the use of any technique other than differential scanning calorimetry to measure melting start temperature, right?
A. Correct.
Q. And that's inconsistent with the specification of the '668, correct?
A. They use DSC as their example.
Q. But they use it as an example, not as a comprehensive list of all the techniques that could be used?
A. I would agree that it just says "for example" in this place. I'm not sure -- I would have to look further to see if they have other statements about DSC in here, but I agree that there it says "for example."
Q. Well, look and see if there's anywhere else that you would like to point me to?
A. Okay. Well, in column 16, they, of course have very specific information about how they measured the melting start temperature using a DSC under certain

as an example of one technique?
A. We were -- I'm going back to our earlier discussion about the "melting start temperature" being ill-defined. Well, it's exactly defined in here.
Q. And they say it can be measured by, for example, DSC, right?
A. That's what it --
MS. TAKAHASHI: Objection. Asked and answered.
A. Yeah.
Q. And your definition requires the use of DSC, correct?
MS. TAKAHASHI: Objection. Asked and answered.
A. As I previously said, that's correct.
Q. Does -- in this specification, do the inventors say at what point along the DSC curve should be interpreted to be the melting start temperature?
A. They don't -- they don't indicate this, but one of ordinary skill with a DSC knows that all DSCs, even back in 1999, come with software that will calculate melting start

temperature as well as peak melting temperature, standard thermal analysis technique.

Q. Just so we're clear, nowhere in the specification is it set out where along the DSC curve should be determined to be the melting start temperature, right?

MS. TAKAHASHI: Objection. Ambiguous. Asked and answered.

A. Well, it says -- it defines "melting start temperature," the temperature at which crystals start to melt when heated, for example, the DSC measurement conditions, which means that when -- which says using a DSC, is when the heat flow curve starts to move detectably off the baseline which is what DSC software measures when it gives you a melting start temperature.

Q. And anywhere in your definition of "melting start temperature," have you included anything to indicate where it is along the DSC curve that melting start temperature should be defined?

A. It's -- again, it's intrinsic in the

measurement device and the detector and the software that's included.

Q. And is it -- and you said a second ago that it's -- it's the point at which there is any measurable movement above the baseline?

A. It --

MS. TAKAHASHI: Objection. Mischaracterizes the witness' testimony.

A. Melting start temperature is clearly when you start to see, in the case of melting, an endotherm off the baseline, but you don't visually detect it again. You use software to detect it.

Q. So it's when there is an endotherm off the baseline, that's the point that you would peg as melting start temperature?

A. It's not what I would peg. It's how it's defined.

I mean, it's how it's defined. It's actually in that USP section. There was a -- we were just looking at it. It defines it exactly the same way.

Q. So any endotherm off the baseline would be the melting start temperature along a DSC

curve?

A. No.

MS. TAKAHASHI: Objection. Mischaracterizes the witness' testimony.

A. No. When you have a full melting peak and you want to know when the melting start temperature is, okay, the DSC software would detect when the melting began, okay, which is when you're getting an endotherm off the baseline.

But you would use the software to detect it, and it would tell you where the peak is, the place where you have the maximum melting, and that would be considered the melting point peak; and it would give you the area under the curve, which is the enthalpy change of melting.

That's how much heat you had to add to do the melting.

Q. Let's go to your declaration, and if you can go to page 12.

A. Right.

Q. And you see paragraph 42, you have a DSC curve?

A. Yes.
Q. And you've taken that from an article, Exhibit 8, entitled "Differential Scanning Calorimetry," the University of Southern Mississippi Polymer Science Learning Center."
Do you see that?
A. Correct.
Q. In your opinion, where along that curve would the melting start temperature be?
MS. TAKAHASHI: Objection. Ambiguous.
A. Well, as I previously have said, at least three times, eyeballing melting start temperature is not particularly appropriate.
However, if you're asking me to eyeball melting start temperature, you have a baseline here that's, in this case, perfectly horizontal and the curve is starting to move off this baseline. There's a standard algorithm, which is included in the DSC software, to analyze the baseline, which is sometimes noisy, and the movement off the baseline to tell you when you have a statistically significant movement off the

baseline on the way up to this -- this peak.

So it's somewhere in this initial region here, when they move off the baseline. Again, I would not by eye give you an exact place.

Q. So for one of skill in the art in 1999 or 2000 would have to not only use DSC but also use a software algorithm with DSC in order to determine, in your opinion, melting start temperature, correct?

MS. TAKAHASHI: Objection. Mischaracterizes the witness' testimony.

A. That's what one of ordinary skill would use because all DSCs in 1999 came with normal analysis packages.

Now, you could -- in years before that, we used to graphically analyze these things, which is still possible, but I don't think anybody in 1999 would be doing that.

Q. Okay. Let's take a look at --

A. I think we're going to see one of my papers.

Q. We might see one of your papers.

A. Yeah. Yeah. I bet I know which one:

the "Solubility Measurement Using [the] DSC." That one?

MR. ACKER: Well, let's take a look. Let's mark this as -- it's going to be 14.

MR. DANE: Don't give him any ideas.

THE COURT REPORTER: Thirteen.

A. I like that one. That's a good paper.

EXHIBIT 13 MARKED

MR. ACKER: Thirteen?

THE COURT REPORTER: It'll be 13.

A. No. Not one of mine.

BY MR. ACKER:

Q. Feel free to look at any portion of the article, Doctor, but I'm going to ask you about figure 1.

A. Okay. I will start out with the fact that I've never seen this article before.

Q. Okay. Fair enough.

If you take a look, it's an article we've marked as Exhibit 13. It's an article by M.E. Brown entitled the "Determination of Purity by Differential Scanning Calorimetry (DSC)," and if you take a look at the second page, down on the bottom right, you see

there's a volume number with the date of May 5th, 1979.

Do you see that?

A. Uh-huh.

Q. You just have to answer yes or no.

A. Yes.

Q. And so this article, it would have been in the art and available for one skilled in the art looking at the '668 patent in 1999 or 2000, correct?

A. Yes.

Q. And if you take a look at the graph, the DSC curve in figure 1, there's a spot there, "T_o."

Do you see that?

A. Yes.

Q. And T_o is defined in this article as the melting point, correct?

A. I don't see that.

Q. If you take a look in the narrative below figure 1.

A. Oh, okay. I see.

Q. So in that line, T_o is near the point where the DSC curve comes off the baseline,

correct?
MS. TAKAHASHI: Objection.
Ambiguous.
A. I would define this as the melting start temperature, myself.
Q. Okay. So, in your opinion, that point T_o in this article would be the melting start temperature, although the authors here have defined it as the melting point, correct?
A. That's correct. In some -- there's some literature where people actually define the melting start temperature as the melting point as opposed to using the peak, which here would be point B, as a melting point.
I think you can go to the literature and find both definitions.
Q. Okay. So when you say the peak -- the second line in figure 1 is labeled B at the top?
A. Right.
Q. A is T_o, and that is defined in this article as the melting point, right?
A. Correct.
Q. But the B line in this figure 1, which

is the peak of the DSC curve, you understand that some folks in the art also label that as the melting point?

MS. TAKAHASHI: Objection. Ambiguous.

A. On occasion. And most accurately, most people report a melting point range which would be A -- T_o at A and C.

Q. But you would agree with me that in the 1999 or 2000 time frame, there was no consistency in the literature as to whether the earlier point, the T_o, or point A in figure 1, or the B, the height of the graph, was labeled as melting point?

MS. TAKAHASHI: Objection. Vague. Calls for speculation.

A. I only know what I knew at that time, which would be that in most analyses that I'm familiar with, people would consider A a melting onset, and they would use B as their melting point; or more accurately, they'd actually report the range.

And, in any case, if A is -- even if you define A as melting point, it's only the

your declaration?
A. Page --
Q. I'm sorry. Here.
A. Page 5, yeah. This one (indicating).
Q. No. At the bottom left, there's numbers.
A. Oh, okay.
Q. And the graph at the top, is it the DSC curve that you have in your declaration, correct?
A. Yes.
Q. And it's labeled T_m, the height of the DSC curve, correct?
A. Right.
Q. And the authors in this article that you rely on refer to that as the melting temperature, T_m, right?
A. Correct.
Q. So they don't call it the "melting point," they call it the "melting temperature," right?
A. They do.
Q. Let me show you another article. We're going to mark this as 14.

EXHIBIT 14 MARKED

A. Yes.

Q. Have you had a chance to look at that?

A. Well, I've never seen it before, but I've look at the title.

Q. Okay. This is an article by a Ronald Amelia -- a D'Amelia, d'-A-M-E-L-I-A, Department of Chemistry, Hofstra University, and if we go down to the -- halfway down or two-thirds of the way down the first column, you see there's a reference to the use of DSC?

A. Yes.

Q. And then if you go to the right column there, you see the paragraph that begins with "All melting point data."

A. Yes.

Q. And it reads, "All melting point data or endothermic transition temperatures are obtained by taking the onset temperature of the endothermic change from the thermal baseline."

Do you see that?

A. Yes.

Q. There's no reference there of "melting

start temperature," correct?
A. No. But "onset temperature" and "start temperature," again, are synonyms.
Q. And in this article, they equate melting point to the onset temperature of the endothermic change, correct?
A. Yes.
Q. So if you take a look at the next page, and if you go down to the graph, figure 1, on the bottom left side.
Do you see that?
A. Yes.
Q. So instead of the melting point being the height of the DSC graph in this article, the melting point is actually where the DSC curve begins to move off of the baseline, right?
A. They're defining that as their melting point, correct.
Q. And, again, there's no reference -- you haven't had a chance to read the article, but you don't see any reference in this article to "melting start temperature," correct?
MS. TAKAHASHI: Objection. Vague.

A. Again, they use the term "onset temperature," which means the same thing.
Q. And they actually point to the area that you would call the "melting start temperature," and they call it the "melting point"?
A. Right. They also call it the "onset temperature."
Q. But don't use the term "melting start temperature," we can agree on that?
A. We can agree that they don't say -- they use a synonym for "start" as "onset."
Q. And they also refer to that point as the "melting point"?
A. Right.
Q. Let me show you another article. Exhibit 15.
EXHIBIT 15 MARKED
Q. You might want to flip those over or you're going to get -- they're going to get lost in a sea of documents there.
A. Uh-huh.
Q. This is an article that you actually relied on in reaching your opinions in this

If something becomes more pure, its melting point goes up and, typically, the melting point range, that is, the difference between the onset temperature and the final temperature declines. The peaks become sharper, although they don't show these getting that much sharper.

I don't believe this indicates anything about the -- what the melting points are because -- I mean, what -- are they using the peak or somewhere else on the curve? It just lists the purity for each of these three.

Q. So looking at this graph, figure 5.4 in the Byrn article you relied on, just looking at the graph, you can't tell where along the graph the Byrn authors decided was the melting point of each of these substances?

MS. TAKAHASHI: Objection. Ambiguous. Mischaracterizes the witness' testimony.

A. Well, what I would -- actually, it says exactly what I would say here, which is -- I just saw it a second ago.

Yeah. It just says, in general, a

Q. Yes, sir.
A. Yes.
Q. And if you go to the third paragraph down that begins with "A limitation."
Do you see that?
A. Yes.
Q. That sentence reads -- or Dr. Brittain wrote, "A limitation of DSC is that although it reveals the existence of thermally induced transitions, the nature of these transitions can be difficult to determine."
Do you see that?
A. Yes.
Q. And you agree with that statement?
A. Well, I mean, it can be. It depends on the sample and the situation.
Q. You also reference a declaration by one of the inventors in the case, a -- I believe it's a doctor, but I'm not sure -- Urai, U-R-A-I, correct?
You reference that declaration?
A. I believe that's correct.
Q. I think it's tab 21 of your materials.
A. Yes.

Q. And in that declaration, Tadashi, T-A-d-A-S-H-I, Urai, U-R-A-I, makes a declaration, and he is one of the inventors of the '668 patent, correct?

A. Yes.

Q. And it looks like he is not a doctor, but has a master's in engineering.

Do you see that? He graduated from --

A. Oh, yeah. I see that. Yeah.

Q. Okay. And then, this is part of the file history, this declaration is part of the file history of the '668 patent, correct?

A. Yes.

Q. And that's the patent that in claims 9 or 10 contains this term "melting start temperature" that we've been discussing, right?

A. Yes.

Q. And in his declaration, Mr. Urai lays out experiments that he conducted to determine the -- what he calls the "melting start temperature" of two samples in an earlier patent, the '058 patent?

MS. TAKAHASHI: Objection.
Misstates the document.
A. Yes. He reports on reference example 4 of the '058 and then crystal example 1 of the '058 and example 2 of the '058.
Q. And if you look at the declaration on the right side, he says, under "method," he writes, or he wrote, "The melting start temperature was measured using DSC," and then he lays out the conditions, correct?
A. Correct.
Q. And DSC is, again, the method that is contained in your claim interpretation of melting start temperature as the method that should be used to determine melting start temperature, right?
A. Yes. And also in the specification of the patent.
Q. And then he sets out the results that he got for melting start temperature for crystal example 1 of -- crystal example 1 of the '058 patent and crystal example 2 of the '058 patent, right?
A. Correct.

Q. And the melting start temperature he got for crystal example 1 of the U.S. -- of U.S. Patent '058 was 128.3 degrees Celsius, right?
A. That's what it says.
Q. And if we go to the '058 patent which is tab 1, okay?
A. Tab 1.
Q. And if you go to column 10.
A. Column 10.
Q. You see example 1 there?
A. Correct.
Q. And there's a melting point range that's listed.
Do you see that, "MP"?
A. Yes.
Q. And it's a range of 144 to 144.5 degrees Celsius, right?
MS. TAKAHASHI: Objection. Misstates the document.
A. Yes. It does say -- give a melting point range of 144.0 to 144.5.
Q. So one of skill in the art reading the '668 patent and its file history would see

that there's a reported melting point range of 144 to 144.5 degrees Celsius for example 1, but there's also a reported melting start temperature for that same example of 16 point -- 16 degrees Celsius lower of 128.3, right?

A. Where is the -- what number is the declaration? I'm sorry.

Q. Twenty-one.

A. They were also clearly different as reported in this declaration as reported in the '058 patent.

Q. Okay. When you say "this declaration," the melting start temperature for example 1 of the '058 patent reported in the file history of the '668 patent is not within the melting range that is reported for that same crystal in the '058 patent, right?

MS. TAKAHASHI: Objection. Ambiguous. Misstates the documents.

A. That's correct. My understanding of this, if we read the material, the resulting crystals according to reference example at 4 is stored at 30 degrees in the chemical development -- minus 30 degrees, chemical

development laboratory -- okay. Same thing.

The resulting crystals according to examples 1 and 2 of U.S. Patent No. 6,462,058 were provided, and, again, this is indicating who gave it to him, and these crystals have been stored at minus 30 degrees C in the Osaka Research Center.

So these are crystals that were prepared and saved.

Q. And when Mr. Urai used DSC to obtain a melting start temperature for example 1, the crystal in example 1 of the '058 patent, he got a reading of 128.3, which is 16 degrees lower than the melting range reported in the '058 patent for that same crystal?

MS. TAKAHASHI: Objection. Vague. Misstates the document.

A. That's correct.

Q. And if we take a look at example -- the reference to the melting start temperature for example 2 of the '058 patent in Mr. Urai's declaration, he used DSC and obtained a melting start temperature of 129.1 degrees Celsius, correct?

A. That's correct.
Q. And if we go to the '058 patent and look at example 2 in column 11, you see there's a melting point range there of 147 to 148 degrees Celsius.
A. Yes.
Q. So one of skill in the art reading the '668 patent and its file history would find that for example 2 of the '058 patent, the melting start temperature is 129.1 degrees, and the melting point is a range of 147 to 148 degrees, right?
A. Well, they would see the -- they would see that the difference between these reported melting points, the melting point range in the patent was substantially different than the melting start temperature reported in the declaration.
Q. And the melting start temperature that was determined by the method that you believe should be the method used to determine melting start temperature, correct?
A. Using the DSC.
Q. And when DSC was used to analyze the

melting start temperature of example 1 and example 2 of the '058 patent, melting start temperatures were obtained that were 16 and 17 degrees lower than the melting point range reported in the '058 patent?

MS. TAKAHASHI: Objection. Misstates the document.

A. Different values were obtained in the declaration than those reported in the patent. That's correct.

Q. And this information, that is, the Urai declaration, would be a part of the file history that one of skill in the art would look to when trying to understand what the term "melting start temperature" meant in the '668 patent, correct?

A. I assume they could. Though, as I previously testified, I think one of ordinary skill would understand what the term means from the patent and the specification.

Q. Let me ask you about the term "about."

The term "about" was another term that you were asked to provide an opinion about it's meaning as part of your work in

Q. Claim 10 reads, "The crystal of claim 9 wherein the melting start temperature is about 135 degrees Celsius."

Do you see that?

A. Yes.

Q. And your definition of "about" is "approximately." So, in your opinion, can you place a -- quantitatively place a number of degrees on what "approximately 135 degrees Celsius" means?

A. Well, in the context of my previous claim construction about melting start temperature being measured with a DSC, okay, and based on one of ordinary skill in the art understanding of how a DSC would work, it would be probably on the order of about .2, .3 degrees C, maximum.

Q. Each way, up and down?

A. Plus or minus, yeah.

Q. So if --

A. I'm sorry. Let me modify my answer to say for repeating identical samples at identical conditions.

Q. Okay. So let me ask it this way.

If there was a compound that was a crystal that met the limitations of claim 9 and it had a melting start temperature of 135.5, do you believe it would fall within the meets and bounds of claim 10?

MS. TAKAHASHI: Objection. Ambiguous.

A. So the question is, would 135.5 meet claim 10?

Q. No. Let me -- I think you just said that in your opinion, "approximately" would allow you to go above or below 135 by .2 degrees Celsius.

A. Correct.

Q. So --

A. I said .2 or .3, actually, but.

Q. .2 or .3?

A. Uh-huh.

Q. So -- and that's the full extent of "approximately" that you would -- as one of skill in the art would put on it? That "approximately" would extend claim 10 up to 135.3 and down to 134.7 degrees Celsius?

A. Correct.

Q. And if a compound had a melting start temperature that was greater than 135.3 degrees Celsius, then it wouldn't fall within the scope of claim 10 under your definition?
A. That's correct.
Q. And similarly, if a compound that met the limitations of claim 9 had a melting start temperature of 134.6, it would not meet the limitations of claim 10?
A. No. That's not correct.
Q. What have I got wrong about that?
A. Because claim 10 says a melting start temperature of not lower than 131 point C. It has no upper range.
Q. No. It says, is "about" 135 degrees Celsius.
A. Not lower than about 131 degrees C. So you can be anything above 131 C.
Q. Yeah. I'm looking at claim 10, not 9.
A. You actually just said "9."
Q. Well, let me start over then.
When I said "9," it's a dependent claim, claim 10. So you have to satisfy all the claim limitations of claim 9.

A F T E R N O O N S E S S I O N

EXHIBITS 16 AND 17 MARKED

THE VIDEOGRAPHER: Back on the record, 1:23 p.m.

BY MR. ACKER:

Q. Good afternoon, Doctor.

A. Good afternoon.

Q. Let me hand you what we've marked as Exhibit 16.

MS. TAKAHASHI: Thank you.

Q. Then I'm going to hand you another document, what we've marked as Exhibit 17, Doctor.

Exhibit 16 is a document we marked that's entitled "Plaintiffs' Responses to Anchen Pharmaceutical Inc.'s First Set of Interrogatories," and I want to direct your attention to, if I might, Interrogatory No. 2 on page 4; and this is a document in which Anchen is asking Takeda to respond to the following question: "Identify all facts supporting Takeda's assertion that Takeda's Dexilant product, which is the subject of New Drug Application (NDA) 22-287, is covered by

the asserted claims of the listed patents identified in Takeda's disclosure of asserted claims and infringement contentions, including but not limited to, any dissolution tests, XRP [sic] analyses, studies, research, and literature."

And if you go down to the response to that question, if you go down to lines 24 and 25, you see there's a reference to claims 9 and 10 of the '688 patent.

Do you see that, Doctor?

A. Uh-huh.

Q. You have to answer yes or no.

A. Yes.

Q. Okay. And then if you go to the next page, page 5, lines 1 and 2, Takeda is responding to that interrogatory saying "NDA No. 22-287 (hereinafter the Dexilant NDA) generally contains facts and analyses that demonstrate that Takeda's Dexilant product satisfied the claims listed above."

And then if you go over to page 6, at lines 6 through 9, you see Takeda responds "SSCI also measured a melting start temperature

of 140 degrees Celsius for the dexlansoprazole drug substance by hot stage microscopy, demonstrating that the Dexilant product meets the limitations of claim 9 and 10 of the '668 patent." And you see there's a reference there to a certain document.
Do you see that, Doctor?
A. Yes.
Q. And then if you take look at exhibit seven -- the other document I handed you, Exhibit 17.
A. Yes.
Q. You see that Exhibit 17 is entitled "Executive Summary."
Do you have that?
A. Uh-huh. Seventeen, yes.
Q. "Executive Summary of TAK-390 Solid State Chemistry," and you see in the title, it says, "A report generated for Takeda Pharmaceutical, Limited, on 12/28/2007."
Do you see that?
A. Yes.
Q. And if you go into the document, under the summary, under the first page --

A. Yes.
Q. -- the first paragraph reads, "This document summarizes multiple studies performed at SSCI, Inc., including a polymorph screen preparation/characterization/physical stability of solid forms [2,3], computational study of the solid forms [4], solubility/chemical study of solid forms [5], and method development of an XRP [sic] limited test for impurity forms B, C, d, and F in TAK-390MR Granules-h [6]."
Do you see that?
A. Yes.
Q. And then if you go down to the third paragraph, it reads in the first sentence there, "In summary, form A is the anhydrous form and is the final form of choice."
Do you see that?
A. "Anhydrous"?
Q. "Anhydrous," yes. Do you see that?
A. Yes.
Q. Okay. And then if we go to page 6 of 19, do you see the B up there? It says "form A."

A. Yes.
Q. It says, "Form A is anhydrous non-hygroscopic crystalline material which melts at 140 degrees Celsius."
A. It actually says 148 degrees.
Q. I'm sorry. "148 degrees Celsius."
Do you see that?
A. Yes.
Q. And then if you go down to the chart below, you see that the melting point of 148 degrees Celsius, that was determined by DSC.
Do you see that?
A. Yeah. There's one DSC, 10 degrees C, data of a major endotherm, 148 degrees C.
Q. But if you go down lower, you see there's a reference to something called "HSM."
Do you see that test?
A. Yes.
Q. And if you go back to the page before, you see there's an abbreviation there for HSM of hot stage microscopy?
A. Yes.
Q. And what is hot stage microscopy?

A. Hot stage microscopy is a technique where you have a stage on a microscope that -- generally, they're programmable stages where you can put a microscope slide that's sealed or unsealed, as you wish, and you can increase the temperature in a desired way, or you can hold the temperature, and you can observe through the microscope the crystal while it's being heated.

Q. So this is another method unlike -- it's different than DSC to determine a melting point of a solid?

A. Right. It's closer -- it's closer in a sense to the capillary method because you're using visual observation as your means of determining whether -- when something starts to melt and when it's completely melted.

But, yes, it's another method.

Q. If you go back to the page with the actual data on it for the crystalline material, you see under the HSM study, it says, "Melt onset at 140 degree Celsius. Melt completed by 145 degrees Celsius."

Do you see that?

A. Yes, I do.

Q. Now, if we go back to the interrogatory, Exhibit 16, and you go to page 6, in lines 6 through 9, Takeda indicated in response to Anchen's interrogatory question, "SSCI also measured a melting start temperature of 140 degrees Celsius for the dexlansoprazole drug substance by hot stage microscopy, demonstrating that the Dexilant product meets the limitations of claims 9 and 10 of the '668 patent."

Do you see that?

A. Yes.

Q. So when Takeda is measuring its Dexilant product to determine whether or not it falls within the claims of claims 9 and 10 of the '668 patent and that whether it meets the melting start temperature, it's not using DSC, but it's using HSM to conduct that measurement, correct?

MS. TAKAHASHI: Objection. Calls for a legal conclusion. Mischaracterizes the documents, and this witness hasn't seen these documents before today.

A. What's referenced in this Exhibit 16 certainly has to do with hot stage microscopy.

What's been measured in the report -- I'm sure if I look at the full report, there might be more information -- is both DSC and hot stage microscopy for measuring a melting start temperature and melting point.

Q. Okay. If we look at page 6 of 10 of the report, for form A, HSM was used to determine a melt onset at 140 degrees Celsius.

Do you see that?

A. It's reported as a melt onset and a melt completed. That's correct.

Q. And under your interpretation of melt start temperature of claims 9 and 10 in the '668 patent, that would not be the proper technique to use to determine a melt start temperature, right?

A. As I previously testified, I would think that a DSC would be proper, and they have this data available.

They don't report it in this table, but they report a DSC measurement, and they only report the major endotherm, but the DSC

trace is part of this report somewhere, or in the appendix, which would allow one to get a melting start temperature from this, as well.

Q. But what they relied on in the interrogatory response to say that they -- that their Dexilant product fell within claims 9 and 10 of the '668 patent was the 140 degree Celsius melt start temperature determined using HSM, correct?

MS. TAKAHASHI: Objection. Calls for a legal conclusion.

A. All I can tell you is that's what they wrote in this interrogatory. I have no other knowledge of why they used that as opposed to something else.

Q. And in your opinion as a scientist, do you think that using a melting start temperature determined by HSM is the proper way to determine whether or not a compound falls within the claims of 9 and 10 of the '668 patent?

MS. TAKAHASHI: Objection. Vague and ambiguous. Calls for a legal conclusion.

A. As I previously testified and wrote in

my expert report, I think the proper way to do this is through DSC.

Q. So a melting start temperature obtained using HSM would not be the proper way to determine whether or not a product fell under claims 9 and 10 of the '668 patent, right?

A. Well, not according to my interpretation of the proper claim construction.

Q. Now, so if Takeda is relying on a melting start temperature obtained by using HSM to claim that its Dexilant product falls within claims 9 and 10 of the '668 patent, in your opinion, that's an improper analysis?

A. I have no --

MS. TAKAHASHI: Objection. Calls for a legal conclusion.

You can answer.

THE WITNESS: Sorry.

A. I have no opinion of what's on Takeda's mind. I mean, I previously testified that I think the proper claim construction involves using a DSC, and that's just my answer to the question.

disputed term 'amorphous compound' to mean 'a noncrystalline solid that lacks the long-range order characteristic of a crystal.'"

Did I read that correctly?

A. Yes.

Q. And that is your opinion?

A. Yes.

Q. Back in paragraph 52 of your declaration --

A. Yes.

Q. -- you also stated that, "I further understand that unless a patentee defines a term differently in the patent specification, either expressly or by clear implication, a claim term generally should be afforded its ordinary and customary meaning as it would be understood by a person of ordinary skill in the art taking into the account the language of the claims themselves and the teachings of the specification."

Did I read that correctly?

A. Yes, you did.

Q. Is it correct that the term "amorphous compound" in claims 1 and 2 of the '282 patent

is not expressly defined in the specification?
A. I don't believe there is a definition expressly in the specification.
Q. Is it true that the specification does not even use the term "amorphous compound"?
A. I would have to look. I don't recall.
Q. Turning back to paragraph 80 in your definition -- or your -- excuse me, your construction of amorphous compound.
A. Yes.
Q. Do I understand your construction correctly to mean that amorphous compound, basically, means a noncrystalline solid?
A. As used in this -- in the '282 patent, that's correct.
Q. In general, is it your opinion that the word "compound" and the word "solid" are synonymous?
MS. TAKAHASHI: Objection. Vague.
A. Compound and?
Q. Solid.
A. No. Not necessarily.
Q. And why is that?
A. There are compounds that are liquid,

solids, or gases.
Q. So it's correct that a compound can be a nonsolid?
A. That's correct.
Q. Am I also correct that a noncrystalline can be a nonsolid?
A. I'm sorry. Could you repeat that?
Q. Am I also correct that a noncrystalline could be a nonsolid?
MS. TAKAHASHI: Objection. Ambiguous.
A. Okay. When -- typically, the term "noncrystalline" is used to describe crystalline or noncrystalline solids; but, clearly, a liquid or a gas are not crystalline either, I mean, but that's not a normal usage.
When you say something -- referring to crystallinity, you're referring to the solid state, generally.
Q. And so it is understood that noncrystalline is essentially a nonsolid?
MS. TAKAHASHI: Objection. Mischaracterizes the witness' testimony.
A. No. That's not what I said at all.

is noncrystalline because that's obvious. Everyone knows that.

Q. Am I correct that there is no express definition in the '282 specification that limits amorphous compound to a solid compound?

MS. TAKAHASHI: Objection. Asked and answered.

A. There's nothing in the '282 patent except the claim and the examples in the specification where they prepare what they call amorphous material.

Q. So it's correct that there's no express definition in the specification limiting amorphous compound to a solid compound?

MS. TAKAHASHI: Objection. Asked and answered.

A. No. There's no definition of amorphous at all in the '282 patent.

Q. And it's also correct that there's no express disavow of amorphous nonsolids in the specification, correct?

MS. TAKAHASHI: Objection. Vague.

A. There's no discussion at all about amorphous nonsolids.

Q. So am I correct that a person of ordinary skill in the art in 1999 would understand that an amorphous compound, as it's claimed in claims 1 and 2 of the '282 patent, could be referring to an amorphous solid or a nonsolid?

A. I don't believe so in interpreting that claim in light of the specification and the examples and their knowledge. I think they would look at the examples that prepare the amorphous material and realize it's amorphous solid.

Q. But according to the plain and ordinary meaning of the term "amorphous compound," a person of ordinary skill in the art would understand that that could be referring to a solid or a nonsolid compound, correct?

A. If one interpreted "amorphous compound" without reference to the specification at all, okay, in a vacuum, that's correct. But one of ordinary skill would read the specification and interpret the term in light of the specification.

Q. Looking at paragraph 81 of your

fact, I would assume that the same material would be in earlier editions, which I don't think I was able to find. So earlier editions of this would have been available.

We quoted my Second Edition in 2001, but I believe in my First Edition, I have the same definition, which would be 1991, but I don't remember that for a fact, and...

Yeah, again, these are -- reference Exhibit 27 is a Fourth Edition. So I'm assuming there is an edition prior to 1999 with the same definition.

Reference 14 would not have been available. That's a relative new book.

Q. Strictly speaking, as the references are identified here, only Exhibits 10 and 11, based on their date, would be available to persons of ordinary skill in 1999, correct?

A. That's correct.

Q. And these references that you have identified here support the understanding of what an amorphous solid is, correct?

A. That's correct.

Q. But the claim term at issue is

"amorphous compound," correct?
A. That's the claim term.
Q. And am I correct that the none of the references you've listed define the exact declaim term "amorphous compound"?
A. No. They all use either "amorphous material" or "amorphous solid."
Q. Is it correct that the '282 patent specification does not use the term "amorphous solid"?
MS. TAKAHASHI: Objection. Asked and answered.
A. No. I believe in the claim, as we're discussing, it uses "amorphous compound," and in the specification and the examples, it just says "amorphous."
Q. Do you understand the reference in the '282 patent specification to be to "amorphous substance"?
A. I would have to look at the specification.
Q. Okay. Let's turn to the '282 patent. I believe that's Exhibit 5 to your declaration. And I believe you reference a couple of

MS. TAKAHASHI: Objection. Ambiguous.

A. Well, it's my opinion that these two examples, they're amorphous substances described in an amorphous solid. So I think they -- the amorphous compound and the amorphous substance, in both cases, is an amorphous solid.

Q. I understand that that's your stated construction, but would you agree with me that whatever "amorphous compound" means in the claims, it must mean something that's as broad as the term "amorphous substance" used in these reference examples?

MS. TAKAHASHI: Objection. Ambiguous.

A. It should mean the same thing, in my opinion.

Q. Okay. Would it mean something more broad than the term "amorphous substance" used in these examples?

A. No. I think it should mean -- it means the identical thing.

MS. TAKAHASHI: Objection.

solids?

A. This definition is certainly not limited to solids.

Q. Am I correct that a person of ordinary skill in the art in 1999 would know that the term "amorphous substance" was not limited to solids?

MS. TAKAHASHI: Objection. Ambiguous.

A. The -- one of ordinary skill would understand, in a vacuum by itself, the term "amorphous substance" could include liquids, vapors, or solids.

However, one of ordinary skill interpreting the statement of amorphous substance in the '282 patent, in these examples, would understand them to be meaning an amorphous solid.

Q. Is the basis for your position that you just stated reflected in paragraph 83 of your declaration?

A. Yes.

Q. Can you explain for me the basis for your statements in paragraph 83?

A. If one evaporates to an oil, okay, it usually means that the evaporation isn't necessarily complete because an oil still has a vapor pressure. So they usually say they evaporated, and the result was an oil.

You always specify when you have an oil because you could keep evaporating, you could keep heating forever and distill the whole material off if that was the case.

So when you say "evaporate to dryness," you mean a solid, as described here.

Q. If you've evaporated to an oil, is it correct that all you would simply need to do would be evaporate further to achieve the solid that's disclosed in the '282 patent?

A. No. Not if the oil was a true liquid. You could just keep evaporating it forever until you had nothing left.

Q. What do you mean by "true liquid"?

A. An oil is a liquid, right? It's just a viscous liquid, right?

If there is no solid -- there is -- if the condition you're working with, no potential for making a solid, you can distill

your opinion that evaporation in reference examples 1 and 2 of the '282 patent would not also, at least possibly, afford an oil, correct?

MS. TAKAHASHI: Objection. Ambiguous. Lacks foundation.

A. As I say, they would have said "oil" if they meant oil.

Q. And is that your only basis for concluding that reference examples 1 and 2 of the '282 patent result in solids?

MS. TAKAHASHI: Objection. Asked and answered.

A. Yeah. I think I've testified to this a number of times.

They -- if somebody produces an oil in an example, they say an oil. If they produce an amorphous solid, they would normally say an amorphous -- in this case, let me make sure I get the language correct -- amorphous substance.

Q. But they didn't say "amorphous solid," correct?

A. No. But, again, it's my interpretation

A. Yes.
Q. Claim 9.
Okay. It references a crystal of dexlansoprazole having a melting start temperature of not lower than 131 C?
Do you see that?
A. Yes.
Q. Okay. Now, how would you go about getting at sample of a crystal of dexlansoprazole to subject to this test?
A. Oh, I would not interpret that to mean a single crystal. It means crystalline dexlansoprazole.
So you normally would not find a single crystal to do a DSC on. You would take a sample of a known mass, which would have multiple crystals.
Q. Okay. And so you would -- you would -- so explain to me how would you then obtain the sample of the dexlansoprazole material for DSC testing as you've defined it in your claim construction?
MS. TAKAHASHI: Objection. Vague.
A. You -- well, I mean, if we were doing

molecules with long-range order and three dimensions"; is that correct?

A. Yes.

Q. Okay. By -- are you intending to limit the meaning of the word "crystal" by using this definition?

MS. TAKAHASHI: Objection. Ambiguous.

A. I guess I'm not sure what you mean by "limit"?

It's the definition of what a crystal is, and in reference to this patent, we're dealing with molecules. So it's a molecular crystal.

Q. So you think the scope and the meaning of "crystal" is equivalent to the scope and meaning of the phrase you've chosen, "regularly repeating pattern of molecules with long-range order and three dimensions"; is that correct?

MS. TAKAHASHI: Objection. Ambiguous. Mischaracterizes the witness' testimony.

A. I'm sorry. Could you repeat that one

you to determine that something is crystalline,
but the -- but those are generally the ways
you would determine if something's a crystal
or not.

Q. And what does "long-range order" mean?

A. It means that this repeating pattern
continues in exactly the same way for lots of
molecules.

Q. How much?

A. Certainly, it would have to be the
number of molecules equal to the minimum size
crystal you can get of something, which in the
case of these organic molecular materials
would be on the order of a couple of microns,
a micron, two microns, and that's still a lot
of molecules.

I have to calculate how many, but
it's many.

Q. And in your proposed construction, what
does "three dimensions" mean?

A. It means the normal usage of three
dimensions, three spatial dimensions.

Q. Now, why is your proposed construction,
or if it is, why is your proposed construction

regularly repeating pattern, et cetera, more helpful than just simply the word "crystal" or "crystalline compound"?

MS. TAKAHASHI: Objection. Calls for a legal conclusion.

A. I don't know. The -- my definition is what a crystal is. So I guess I'm not sure I know why.

I mean, that is what a crystal is. So it's a description of what a crystal is.

Q. Now, if we look at -- I think we still have '058 patent. If we go back, I think, to example 10 -- or example 1 on column 10.

A. I'm sorry. The '058?

Q. '058, yes.

MS. TAKAHASHI: That's the right one.

THE WITNESS: This is it?

MS. TAKAHASHI: Yeah.

THE WITNESS: Okay. I got it.

Q. It's Exhibit 1 to your declaration.

A. Okay.

THE WITNESS: Column 10?

MS. TAKAHASHI: Yeah.

Q. Column 10.
A. Okay.
Q. I think we talked a little bit about example 1 where we said "after a crystal began to form."
A. Yes.
Q. Would it be appropriate to simply say after a repeating -- regularly repeating pattern of molecules with long-range order and three dimensions began to form, diethyl ether was added and the container was stoppered and kept standing at room temperature?
A. If you wanted to be very wordy. I mean, it means the same thing.
Q. So what the inventor, or someone, observed in example 1 that they called a crystal, you're saying it would've -- the same thing would be they observed a regularly repeating pattern of molecules with long-range order in three dimensions?
That's what they meant?
MS. TAKAHASHI: Objection. Calls for a legal conclusion. Asked and answered.
A. That is the definition of a crystal.

Q. Well --
A. So what I am saying is, if you -- if you substitute the definition of a crystal for the word "crystal," you end up saying exactly the same thing.
Q. Well isn't -- isn't regularly repeating pattern of molecules with long-range order and three dimensions a characteristic of a crystal?
A. That's exactly what a crystal is.
Q. Well, let's turn to your definition of "amorphous compound."
You say that an amorphous compound as used in the '282 patent, it means "a noncrystalline solid that lacks the long-range order characteristic of a crystal."
A. That's correct.
Q. So isn't it fair to say that this long-range order that you're talking about is a characteristic of a crystal?
MS. TAKAHASHI: Objection. Argumentative. Calls for a legal conclusion.
A. It's the definition of a crystal. If you don't have the long-range order, it's not

a crystal.
Q. So did I mean your -- did I misread your -- then why did you choose the word "characteristic" when you -- when you offered a definition for "amorphous compound," why did you call the long-range order a "characteristic of a crystal"?
MS. TAKAHASHI: Objection. Ambiguous. Argumentative.
A. Well, it is a characteristic of a crystal because it is the definition of a crystal.
Q. Thank you.
I'm trying to avoid going over things that you've already addressed. So I apologize for that.
MS. TAKAHASHI: Take your time, Don.
Q. In your definition of "amorphous," you state -- the definition you chose was "a noncrystalline solid that lacks the long-range order characteristic of a crystal."
A. Yes.
Q. Why didn't you say "a noncrystalline solid that lacks the long-range order

characteristic of a regularly repeating pattern of molecules with long-range order in three dimensions"?

A. That's redundant because I'm already referring to the long-range order. I mean, those are synonyms of what a crystal is.

Q. Why didn't you say "a nonregularly repeating pattern of molecules with long-range order and three dimensions that lacks the long-range order characteristic of a regularly repeating pattern of molecules with long-range order in three dimensions"?

A. Because that's a horribly -- that's a horrible sentence, number one; and, number two, it's saying the exact same thing twice, okay.

So in a sense, you could say crystals are shorthand for the long-range three-dimensional order. So -- and that's what I'm describing.

Q. Prior to 2000, did the phrase "amorphous solid" exist?

A. Yes.

Q. Okay. So if the inventors wanted to

refer to an amorphous solid, they could have -- they would have been familiar with the term "amorphous solid," correct?

MS. TAKAHASHI: Objection. Assumes facts not in evidence.

A. The term "amorphous solid" existed. That's correct.

Q. On page 23 of your declaration, which is Exhibit 12 --

A. Page 23?

Q. I'm sorry. Paragraph 23.

A. Paragraph 23.

Q. Strike that. You've already answered that.

Let's go to paragraph 57 of your declaration.

A. Yes.

Q. I think -- you have a number of exhibits that you think support your definition of the term "crystal," and they're listed in the table that begins on page 15; is that correct?

A. Yes.

Q. Okay. And I assume that the -- the far

CERTIFICATE

COMMONWEALTH OF MASSACHUSETTS)
COUNTY OF SUFFOLK)

I, Deborah Roth, a Registered Professional Reporter and Notary Public duly commissioned and qualified in and for the Commonwealth of Massachusetts, do hereby certify: That Allan Myerson, Ph.D., the witness whose deposition is hereinbefore set forth, was duly identified and sworn by me, and that the foregoing transcript is a true record of the testimony given by such witness to the best of my ability.

I further certify that I am not related to any of the parties in this matter by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 17th day of November 2011.

Deborah Roth

Deborah Roth, CSR: 14700-S, RPR: 34250

My Commission Expires: January 23, 2015